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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,118	10/30/2001	Stanford Mark Moran	BMED-004/01US	8022
23419 7590 03/18/2004				
COOLEY GODWARD, LLP				
3000 EL CAMINO REAL				
5 PALO ALTO SQUARE				
PALO ALTO, CA 94306				
EXAMINER				
ANDRES, JANET L				
ART UNIT		PAPER NUMBER		
1646				

DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/004,118

Applicant(s)

MORAN, STANFORD MARK

Examiner

Janet L. Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-54 and 65-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-54 and 65-67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### **RESPONSE TO AMENDMENT**

1. Applicant's amendment filed 19 December 2003 is acknowledged. Claims 1-54 and 65-67 are pending and under examination in this office action.

#### ***Claim Rejections/Objections Withdrawn***

2. The rejection of claims 41-54 under 35 U.S.C. 102(b) is withdrawn in response to Applicant's amendment to the claims.
3. The rejection of claims 1-3, 8, 10, 14-19, 21-24, 28, 30, and 34-40 under 35 U.S.C. 103(a) as unpatentable over Palmeri et al. in view of Corless and Hauser is withdrawn in response to Applicant's amendment requiring a particular delivery system and arguments that there is no motivation to combine these references. Applicant's arguments with respect to Palmeri are addressed below.
4. The rejection of claims 4-7, 9, 12, 13, 20, 25-27, 29, 32, and 33 under 35 U.S.C. 103(a) as unpatentable over Palmeri, Corless, and Hauser in view of Johnson et al. is withdrawn for the reasons set forth above.
5. The rejection of claims 11 and 31 under 35 U.S.C. 103(a) as unpatentable over Palmeri, Corless, and Hauser, in view of Kwan is withdrawn for the reasons set forth above.

#### ***New Grounds of Rejection***

6. Claims 1-3, 8, 10, 14-19, 21-24, 28, 30, 34-40, and 41-54, and new claims 65-67 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. patent 5,207,752 (Sorenson et al., 1993) in view of Palmeri et al, cited in the previous office action, and U.S. patent 6,436,091 (Harper et al., filed 1999).

The '752 patent teaches a device and methods for introducing a therapeutic agent for a first interval, then introducing the same agent at a second lower level, in order to achieve and maintain optimal drug levels. See column 2, lines 10-21. Interferons are taught in column 7, line 1. The '752 patent fails to teach the use of this system for optimization of the second dosage level, as is instantly claimed. Palmeri et al., cited in the office action of 14 July 2003, teaches the need for modulation of interferon  $\alpha 2a$  to reduce side effects. Palmeri et al. teaches administration of different levels of interferon to achieve an optimal dosage. It would have been obvious to one of ordinary skill in the art to combine the teachings of the '752 patent with those of Palmeri et al. to optimize interferon doses to reduce side effects. One of ordinary skill would have been motivated to do so because the '752 patent teaches a method of drug administration that allows the achievement and maintenance of preferred dose levels, and Palmeri et al. teaches a situation requiring such optimization. Thus one of ordinary skill would expect system of the '752 patent to be useful for solving the problem presented by Palmeri et al.

The '752 patent also fails to teach internal pumps. The '091 patent teaches osmotic, implantable pumps that can be regulated. See column 2, lines 50-56. It would have been obvious to one of ordinary skill in the art to substitute the pump taught by the '091 patent for that taught by the '752 patent; one of ordinary skill would have been motivated to do so because they have the same function and would be expected to be useful for the same purposes.

7. Claims 4-7, 9, 12, 13, 20, 25-27, 29, 32, and 33 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over the '752 patent in view of Palmeri et al., the '091 patent, and Johnson et al., cited in the previous office action.

The '752 patent, Palmeri et al., and the '091 patent teach as set forth above but fail to teach the claimed interferons, formulations, or diseases. As is set forth in the office action of 14 July 2003, Johnson et al. teaches these diseases and interferons. It would be obvious to one of ordinary skill in the art to combine the teachings of the references cited above with those of Johnson et al. to optimize doses for treatment of other disease. One of ordinary skill would be motivated to do so because Palmeri et al. teaches that interferon  $\alpha$  2 has toxic side effects and provides means to minimize them, and Johnson et al. similarly teaches on p. 72 that interferons  $\alpha$ ,  $\beta$  and  $\gamma$  have serious side effects that limit their use. It would further be obvious to one of ordinary skill in the art to use different interferons that act similarly for the same purpose, as is claimed in claims 9, 12, 13, 29, 32, and 33 because, as stated previously, Johnson et al. teaches that they have similar functions.

8. Claims 11 and 31 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over the '752 patent in view of Palmeri et al., the '091 patent, and U.S. patent 4,847,049, cited in the previous office action. None of the references cited above explicitly teach administration in different formulations. However, the devices of the '091 patent allow for independent administration of two different factors. The '049 patent teaches a pharmaceutical composition of interferons that retards microbial growth for longer than four weeks and teaches the advantages of such compositions. It would be obvious to one of ordinary skill in the art to combine the teachings of the '049 patent with those cited above to use this formulation in combination with other formulations. One of ordinary skill in the art would have been motivated

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to do so because Palmeri et al. and the '752 patent teach short-term treatment followed by long-term treatment, and the devices the '091 patent allow for the use of different formulations. Thus one of ordinary skill would readily appreciate that two different formulations could be used for the two different terms taught by Palmeri et al.

With respect to the teachings of Palmeri, Applicant argues that Palmeri does not teach optimization in a single individual and teaches only one formulation.

Applicant's arguments have been fully considered but have not been found to be persuasive. Applicant's claims encompass single formulations; thus the single formulations taught by Palmeri do not teach away from what Applicant has claimed. Other formulations and the motivation to use them are provided by the '091 patent. That Palmeri teaches optimization in treatment groups does not render optimization in an individual non-obvious. Palmeri clearly teaches that individuals experience adverse reactions that are dose limiting, thus there is motivation to optimize the doses that individuals receive. The '752 patent provides a means for doing so.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday-Thursday and every other Friday, 8:00-5:30.

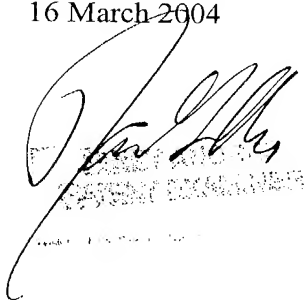
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres, Ph.D.  
16 March 2004

A handwritten signature in black ink, appearing to read "Janet L. Andres", is written over a faint, rectangular stamp. The signature is fluid and cursive.